Pharmacy Compounding Advisory Committee

October 14, 15, and 16, 1998
Advisory Committee Conference Room, 1066
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

DRAFT AGENDA

Objectives:

1. Introduce certain issues associated with implementation of Section 127 of the FDA Modernization Act on Pharmacy Compounding

2. Review bulk drug substances nominated for inclusion on a list of bulk drug substances that may be used in compounding that qualifies for the applicable statutory exemptions that are neither components of FDA approved products nor covered by a United States Pharmacopeia/ National Formulary monograph.

3. Review drug products proposed for inclusion on a list of products that have been withdrawn or removed from the market for reasons of safety or effectiveness that may not be used in compounding that qualify for the applicable statutory exemptions.

Day 1: Wednesday, October 14, 1998

8:30 a.m.	***Call to Order/General Introductory Remarks***	*Dr. Juhl*
	Conflict of Interest	*Ms. Topper*
8:50 a.m.	Introductory Remarks	*Dr. Woodcock*
9:00 a.m.	**Presentations from Invited Speakers**	
	Kate Lambrew Hull, Legislative Assistant, Senator Tim Hutchinson	
	American Pharmaceutical Association	

	International Academy of Compounding Pharmacists	
	Pharmaceutical Research and Manufacturers of America	
	Generic Pharmaceutical Industry Association	
	Public Citizen Health Research Group	
10:00 a.m.	***Break***	
10:10 a.m.	FDA Overview of Pharmacy Compounding Legislation	*Jane Axelrad/Lana Ogram*
10:30 a.m.	Criteria for Selection of Bulk Drug Substances for List	*Robert Tonelli*
12:00 p.m.	***Lunch***	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Introduction of Bulk Drug Nominations	*Robert Tonelli*
2:10 p.m.	Discussion of Bulk Drug Nominations and Presentations from Nominators	
3:00 p.m.	***Break***	
3:10 p.m.	Discussion of Bulk Drug Nominations and Presentations from Nominators	
5:00 p.m.	***Adjourn***	

Day 2: Thursday, October 15, 1998

8:30 a.m.	***Call to Order***	
8:40 a.m.	Discussion of Bulk Drug Nominations	
10:00 a.m.	***Break***	

10:15 a.m.	Discussion of Bulk Drug Nominations	
12:00 p.m.	***Lunch***	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Discussion of Proposed List of Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness	*George Scott*
3:00 p.m.	***Break***	
3:10 p.m.	Discussion of Proposed List of Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness	
5:00 p.m.	***Adjourn***	

Day 3: Friday, October 16, 1998 (If necessary)

8:30 a.m.	***Call to order***
8:40 a.m.	Discussion of Proposed List of Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness
10:00 a.m.	***Break***
10:10 a.m.	Discussion of Proposed List of Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness
12:00 p.m.	***Lunch***
1:00 p.m.	Open Public Hearing
2:00 p.m.	Discussion of Proposed List of Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness
3:30 p.m.	Closing Remarks and Adjourn